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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,098	08/28/2001	Lance E. Steward	17451 (BOT)	6185

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 06/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/942,908	Applicant(s) Steward et al
	Examiner Patricia A. Duffy	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-95* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Prior to setting forth the restriction requirement, it is noted out that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the method and products rely upon substrates that have mutually exclusive characteristics, because each toxin cleaves a different peptide bond and therefore require non-coextensive searches to such an extent that they are considered not to share a structural feature in common.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-3, 4-8 and 45-66 (in part) drawn to a substrate for botulinum toxin serotype A, classified in class 530, subclass 402.
2. Claims 1, 2, 9-13 and 45-66 (in part), drawn to a substrate for botulinum toxin serotype B, classified in 530, subclass 402.
3. Claims 1-3, 14-20 and 45-66 (in part) , drawn to a substrate for botulinum toxin serotype C1, classified in 530, subclass 402.
4. Claims 1-3, 21-25 and 45-66 (in part) , drawn to a substrate for botulinum toxin serotype D , classified in 530, subclass 402.
5. Claims 1-3, 26-30 and 45-66 (in part) , drawn to a substrate for botulinum toxin serotype E , classified in 530, subclass 402.
6. Claims 1-3, 31-35 and 45-66 (in part) , drawn to a substrate for botulinum toxin serotype F, classified in 530, subclass 402.
7. Claims 1-3, 36-39 and 45-66 (in part) , drawn to a substrate for botulinum toxin serotype G, classified in 530, subclass 402.
8. Claims 1-3, 40-44 and 45-66 (in part) , drawn to a substrate for tetanus toxin, classified in 530, subclass 402.

9. Claims 68-70 and 78-95 (in part), drawn to a method using substrates for botulinum toxin serotype A, classified in class 435, subclass 7.4.

10. Claims 68-69, 71 and 78-95 (in part), drawn to a method using a substrate for botulinum toxin serotype B, classified in class 435, subclass 7.4.

11. Claims 68-69, 72 and 78-95 (in part), drawn to a method using a substrate for botulinum toxin serotype C1, classified in class 435, subclass 7.4.

12. Claims 68-69, 73 and 78-95 (in part), drawn to a method using a substrate for botulinum toxin serotype D , classified in class 435, subclass 7.4.

13. Claims 68-69, 74 and 78-95 (in part), drawn to a method using a substrate for botulinum toxin serotype E , classified in class 435, subclass 7.4.

14. Claims 68-69, 75 and 78-95 (in part), drawn to a method using a substrate for botulinum toxin serotype F, classified in class 435, subclass 7.4.

15. Claims 68-69, 76 and 78-95 (in part), drawn to a method using a substrate for botulinum toxin serotype G, classified in class 435, subclass 7.4.

16. Claims 68-69, 77 and 78-95 (in part), drawn to a method using a substrate for tetanus toxin, classified in class 435, subclass 7.4.

3. Inventions 1-8 are related as toxin substrates. However, the toxin substrates lack a common core structure and are therefore chemically distinct. In the instant case the

different inventions define different substrates that lack structure in common and can not be interchanged. For example, serotype A requires a Gln-Arg bond, serotype B requires a Gln-Phe bond, serotype C requires a Lys-Ala bond, serotype D requires a Lys-Leu bond. These different bonds define the substrate specificity for cleavage sites for each of the individual toxins. As such, a search for one substrate comprising a cleavage site would not reveal art on the other cleavage sites and as such are mutually exclusive and distinct as claimed.

4. Inventions 9-18 are related as method of use of toxin substrates. The methods are distinct as claimed because they rely upon toxin substrates that are distinct as set forth *supra.*

5. Inventions (1-8) and (9-18) respectively are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product (i.e. a method of detection) can be practiced with a materially different product such as a serotype specific monoclonal antibody.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for Group 1 is not required for Group 2-8 and vice versa, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
June 8, 2003

Patricia A. Duffy

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600